IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

KATHY MCCORNACK, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:09-cv-00671

ACTAVIS TOTOWA, LLC. et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending is the plaintiffs' motion to set trial date and amend scheduling order [Docket 79].[1] The plaintiffs request (1) that the trial be set for June 4, 2012, or as soon as possible thereafter; (2) that they be granted a seven-month extension of case-specific fact discovery and related case management deadlines found in the November 30, 2010, scheduling order; and (3) that they be permitted to depose Robert Wessman, the former chief executive officer of Actavis Group hf.

I. FACTS AND ARGUMENT

On March 23, 2008, Daniel McCornack suffered a fatal heart attack. He was taking a prescribed course of Digoxin at the time. He had taken the drug without incident for a decade. His family learned of the Digitek recall a few weeks following his death. When the coroner learned of

[1]The plaintiffs requested a hearing on this and three other motions. I find that a hearing is unnecessary to resolve the matter.

the recall, he had Mr. McCornack's blood tested for Digoxin. The elevated post mortem reading caused an amendment to the autopsy report. The coroner concluded that death was caused by Digoxin poisoning.

On June 12, 2009, this case was directly filed in the MDL. Two months later, it was selected as one of ten initial trial cases and active discovery began. In November 2009 that group of ten was narrowed to five. This action was not selected as a "representative" case due to the unique issue of post mortem Digoxin levels. On August 12, 2010, I stayed discovery during the MDL settlement negotiations. On November 19, 2010, the stay was lifted. On November 30, 2010, I entered an individual scheduling order for this case. The parties were to complete basic, case-specific fact discovery, including depositions, no later than May 2, 2011. After submission of plaintiffs' case-specific causation expert reports on May 16, 2011, the parties were to complete depositions of those experts no later than June 15, 2011. As the defendants note in their response, the November 30, 2010, scheduling order was a balanced roadmap. It accommodated plaintiffs' counsels' schedule and workload while at the same time dovetailing with the general Case Management Order applicable to the other remaining cases in the MDL after the Settlement Agreement opt-out process.

The plaintiffs' assert that they have been diligent but unable to complete certain discovery. They blame the failure on a combination of (1) their late entry into the MDL, (2) the burden of reviewing and analyzing discovery, (3) bifurcation of general and case-specific discovery, (4) the stay of discovery during MDL settlement negotiations, and (5) issues with end-user batch identification and depositions. The case was filed in June 2009. They complain of receiving only seven-and-a-half months to finish their case-specific discovery. They note also that, during that time, their five-lawyer firm had to try three unrelated matters in other courts.

With the exception of Mr. Wessman's deposition, they say their proposed additional discovery is entirely case-specific. It includes completion of pending batch identification discovery, first propounded in April 2011. They want to find out the particular batch number of Mr. McCornack's Digitek pills and those of the immediately preceding and succeeding batches. They then want to identify all records related to those batches and perform certain tests to develop information on non-active components and attributes such as bio-availability, granulation, blending and fillers. They claim they advised me upon entry of the November 10, 2010, scheduling order that more discovery time would likely be needed due to their busy trial calendar.

The defendants disagree across the board. They accuse plaintiffs' counsel of inexcusable delay and multiplication designed to allow the chasing of a new theory that, despite ample time, was not developed earlier. They also point out that information sought from Mr. Wessman and other sources is really general liability discovery, the period for which has long since concluded. In sum, defendants want to keep the schedule they diligently followed and argue good cause is lacking for a modification since plaintiffs have had, since the beginning of the litigation, the information and facts they need to pursue this "ill-fated new theory." Defs. Br. in Oppos. at 1.

II. DISCUSSION

A. Governing Standard

Federal Rule of Civil Procedure 16(b)(4) controls the modification of a scheduling order. It states that "[a] schedule may be modified only for good cause and with the judge's consent." Fed.

R. Civ. P. 16(b)(4). In its unpublished opinion in *Montgomery v. Anne Arundel Cnty.*, No. 05-1267, 2006 WL 1194308 (4th Cir. May 3, 2006), the Fourth Circuit said Rule 16(b)'s good cause standard focuses on "the diligence of the moving party." *Id.* at *5. It is a theme found in many cases both within and outside this circuit. *See, e.g.*, *Essential Housing Mgt, Inc. v. Walker*, No. 97-2150, 1998 WL 559349, at *4 (4th Cir. Jun. 9, 1998) ("This standard primarily considers the diligence of the party seeking to amend, rather than simply that party's lack of bad faith or the lack of prejudice to the opposing party."); *Advanced Software Design Corp. v. Fiserv, Inc.*, 641 F.3d 1368, 1381 (Fed. Cir. 2011)("Under the good cause standard, the threshold inquiry is whether the movant has been diligent."); *Morrison Enterprises, LLC v. Dravo Corp.*, 638 F.3d 594, 610 (8th Cir. 2011) ("The primary measure of good cause is the movant's diligence in attempting to meet the order's requirements.").

The leading commentators on the Federal Rules of Civil Procedure make these important observations:

> Experience shows that many more motions seeking modification of scheduling orders are denied than are granted, however. Thus, for example, the good-cause standard will not be satisfied if the court concludes that the party seeking relief (or that party's attorney) has not acted diligently in compliance with the schedule. Attorney neglect or inadvertence will not constitute good cause supporting modification. A party's assertion that further discovery is needed, without more, will not suffice. Similarly, the failure to explain satisfactorily delays that led to the need for modification will result in a refusal to modify the order.

6A Charles A. Wright *et al., Federal Practice and Procedure* § 1522.2 (3d ed. elec. 2011).

B. Analysis

This case seems riddled with a lack of diligence. First, plaintiffs' counsel did not move to extend the scheduling order until over a month after the case-specific discovery deadline expired. Second, plaintiffs want to identify the batch number of the Digitek tablets Mr. McCornack took but they failed to even submit a request for third-party depositions on the subject until April 11, 2011.[2] That was less than a month before expiration of the applicable deadline. They could have done so at any time between August 2009, when active discovery commenced, through August 2010 when the stay of discovery was entered. In addition to that generous allotment, they had from November 30, 2010, when the scheduling order was entered, through the close of fact discovery in May 2011.

So plaintiffs had seventeen months to crystallize and develop the theory they now offer. Plaintiffs offer no specific reason for delay beyond "investigation and discovery have now revealed multiple problems with the Actavis manufacturing facility and procedures, and it appears that the 0.25 mg. tablets prescribed to Mr. McCornack likely suffered a defect caused by improper mixing of ingredients and/or improper use of materials or the compaction of materials causing the Digitek tablets to release too much active ingredient. These issues were not known or explored by the

[2]Defendants' supplemental brief in opposition notes that the Caremark pharmacy deposition was scheduled and postponed several times. After defense counsel allegedly made repeated inquiries as to the reason it was cancelled in June, plaintiffs' counsel revealed that the pharmacy had produced a limited set of documents in lieu of appearance and testimony. After defense counsels' further inquiries and threats of seeking court intervention, plaintiffs' counsel produced the documents. While both parties note flaws in the production, the declaration from the Director of Operations at Mr. McCornack's pharmacy seems to narrow down the batches Mr. McCornack ingested to two. Batch records for those Digitek batches were produced and available to plaintiffs' counsel two years ago.

Steering Committee and Plaintiffs need additional time to complete this discovery." (Pl. Mem. in Supp. at 9).

In their reply brief the plaintiffs assert that "[g]iven adequate time, [they] will be able to show Mr. McCornack's death arose out of a manufacturing defect...." (P. Reply at 3). Proving a manufacturing defect has been the key issue in this case, and every case in the MDL, since the beginning.

The bio-availability study for Digitek was apparently one of the first documents produced in this litigation as part of the abbreviated new drug application ("ANDA") filed with the Food and Drug Administration. Despite having nearly two years to review batch records, production procedures, product specification and bio-availability data, and develop all possible theories of attack, none of the plaintiffs' general liability experts offered any opinion on bio-availability. Further, the theory was not developed when the pharmaceutical general liability experts for Plaintiffs' Steering Committee were deposed in January 2011. Plaintiffs' counsel helped prepare for and attended those depositions. The plaintiffs' case- specific expert in this area has been retained since August of 2009. That was prior to depositions of most of the Actavis witnesses and the pharmaceutical general liability experts. There is again no explanation offered why counsel failed to ask questions or seek further information on the bio-availability theory at any of those depositions.

As noted, part of counsels' argument for extending the discovery deadlines is to allow identification of certain batch numbers so that pills from those batches may be tested. The plaintiffs have had 97 or more of Mr. McCornack's very own unused Digitek tablets in their possession since the day this case was filed. That is akin to searching every roof in a neighborhood for leaks in order

to ascertain if one's own roof is waterproof. It actually cuts against a finding of diligence. Counsel could have tested those readily available pills long ago and compared the results to the ANDA information.

The same is true of the requested discovery of Mr. Wessman. The plaintiffs seek to depose him on the issue of decisions surrounding the recall. Mr. Wessman was identified in a May 2009 set of responses to interrogatories as one of five people within the defendants' organizations that was involved, directly or indirectly, in the recall decision. Counsel never sought to depose him during the 13-month period for questioning Actavis company witnesses.

The only apparent basis for seeking this testimony is the statement by Phyllis Lambridis, an Actavis Inc. employee, that Mr. Wessman agreed to recall all lots of Digitek. But that testimony was given during her deposition on January 18, 2010, more than four months before the deadline for company witness depositions and seven months before the court stayed discovery in August 2010. The plaintiffs chose not to explore, or even inquire about, Mr. Wessman's involvement until filing untimely documents to depose him in March 2011.

This failure is troubling for another reason. On November 17, 2010, during a Mandatory Docket Conference, plaintiffs' counsel raised the possibility of additional discovery about "some of the timing of the recall . . .[and] about who made that final decision." (Hrg. Trans. Dckt. 474 at 14). He also expressed his opinion that the PSC discovery had not gone far enough into fact issues regarding the scope of the recall. The court clearly noted that the period for deposing company employees had ended on June 1, 2010. I further observed that "there was always the opportunity for each individual plaintiff's lawyer to suggest questions" and "to contact members of the PSC with regard to discovery they thought necessary." *(Id*. at 15). Defense counsel noted at the hearing that

one of plaintiffs' lawyers even wrote to him in the fall of 2009 with a specific inquiry he wanted to make about the recall. Don Ernst wanted to know "why all lots [were recalled] and why the .25-milligram as opposed to just the .125." (*Id.* at 16). Defense counsel pointed out to plaintiffs' counsel that the issue he raised constituted general discovery and that the period for such discovery was about to kick-off.

Plaintiffs' counsel unquestionably identified, as early as fall of 2009, the scope-of-recall issue but demonstrated lack of diligence in pursuing the foundational information they now seek. Their attempt at this stage in the process to attribute fault to shortcomings on the PSC's part is no substitute for good cause.

The plaintiffs have not provided cause much less good cause to either modify the discovery schedule or delay the dates for expert discovery and the briefing and hearings of the *Daubert* and dispositive motions. Plaintiffs have had months to do case specific discovery. Plaintiffs did not diligently pursue opportunities or the issues they now wish to take up within established time frames. For these reasons, the motion to amend the scheduling order is **DENIED**. A trial date, if needed, will be set after decisions on dispositive motions in accordance with the original schedule of events contemplated by the court. Accordingly, the plaintiffs' motion for setting a specific trial date is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Memorandum Opinion and Order to counsel of record and any unrepresented party.

ENTER: July 25, 2011

Joseph R. Goodwin, Chief Judge